

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALNYLAM PHARMACEUTICALS,)	
INC.,)	
)	
Plaintiff,)	
)	
v.)	C. A. No. 22-335-CFC
)	
MODERNA, INC., MODERNATX,)	
INC., and MODERNA US, INC.,)	
)	
Defendants.)	

**REPLY TO DEFENDANTS' OPPOSITION TO ARBUTUS BIOPHARMA
CORP. AND GENEVANT SCIENCES GmbH'S MOTION FOR LEAVE TO
FILE AMICUS CURIAE BRIEF IN SUPPORT OF PLAINTIFF**

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In opposing Arbutus and Genevant’s motion for leave to file an *amicus curiae* brief on an important legal issue before this Court, Moderna is asking that the Court rule on its motion to dismiss without the benefit of considering that twenty-page brief—and therefore to have less information about the application of 28 U.S.C. § 1498 and the potential implications of its decision. If it were really true, as Moderna asserts, that the legal issues raised in the amicus brief were irrelevant to the case at bar, the Court could have figured that out without briefing on this opposed motion that is now almost as long as the brief Moderna does not want the Court to read.

As explained below, the proposed brief plainly meets the “most lenient standard” governing leave to file, which imposes only the “broadly interpreted” criteria of demonstrating an adequate interest in the case and providing relevant and desirable information to the court. *In re Weinstein Co. Holdings, LLC*, No. BR 18-10601-MFW, 2020 WL 1320821, at *1 n.3 (D. Del. Mar. 20, 2020), *aff’d sub nom. In re Weinstein Co. Holdings LLC*, 997 F.3d 497 (3d Cir. 2021) (citing *Neonatology Assocs., P.A. v. Comm’r*, 293 F.3d 128, 133 (3d Cir. 2002) (Alito, J., granting leave to file amicus brief)). None of Moderna’s arguments counsel otherwise.

I. Legal Standard

In citing the various legal guidance that courts rely on when weighing their discretionary authority to accept an *amicus curiae* brief, Moderna omits the critical

point that the standard for acceptance is low: “Courts will exercise their discretion to allow an *amicus curiae* brief to be filed if rule 29 of the Federal Rules of Appellate Procedure is satisfied by demonstrating, ***under the most lenient standard***, that (1) the movant has an adequate interest in the appeal; (2) the information supplied is desirable; and (3) the information being provided is relevant.” *Id.* (citing *Neonatology Assocs.*, 293 F.3d at 133) (emphasis added). Such motions “should be granted unless it is obvious that the proposed briefs do not meet” Rule 29’s criteria “as broadly interpreted.” *Id.* That decision is one “entirely within the court’s discretion.” *Wortham v. KarstadtQuelle AG*, 153 F. App’x 819, 827 (3d Cir. 2005); *see also Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, C.A. No. 20-1630-RGA-JLH, D.I. No. 74 (D. Del. Aug. 20, 2021).

II. The Proposed Brief Is Proper and Would Aid This Court’s Decision on Moderna’s Section 1498 Defense

Both the present case and the *Arbutus* action raise an important legal issue regarding Moderna’s unprecedented attempt to apply section 1498(a) as a basis to shift its liability for patent infringement onto the United States government for a healthcare product that was provided generally to the American public. Under the governing standard for granting leave to file an amicus brief, *Arbutus* and *Genevant* plainly have an interest in this Court’s decision concerning whether section 1498(a) applies to Moderna’s alleged patent infringement at all, as well as whether that question can be decided at this stage of the litigation. And the proffered brief

provides “desirable” and “relevant” information about the section 1498(a) affirmative defense and its applicability to this situation. *See Neonatology Assocs.*, 293 F.3d at 131 (reciting Fed. R. Civ. P. 29 factors for accepting amicus briefs); *In re Weinstein Co. Holdings, LLC*, C.A. No. BR 18-10601-MFW, 2020 WL 1320821, at *1 n.3 (same). Nothing more is required to grant Arbutus and Genevant’s motion, and none of Moderna’s arguments are to the contrary.

First, contrary to Moderna’s assertion (D.I. 19 (“Opp.”) 4), the fact that Alnylam’s complaint in this action is not identical to the *Arbutus* complaint does not render the proposed brief irrelevant or unhelpful. Moderna chose to assert the same section 1498(a) affirmative defense in response to both complaints by filing a nearly verbatim motion to dismiss. And because Moderna is a party in both actions, its claims of prejudice from the timing or content of the proposed amicus brief (Opp. 4-5) ring hollow. Moderna has already drafted and filed a publicly available response to the proposed amicus brief in the *Arbutus* action.

Second, the proposed amicus brief is not an “improper and untimely extension of plaintiff’s opposition brief” (Opp. 4) any more than **any** amicus brief expands on a relevant legal issue beyond what appears in the parties’ briefing. That is the entire point of an amicus brief. Alnylam had nothing to do with the content of Arbutus and Genevant’s brief, and Moderna identifies no information suggesting otherwise.

Third, Moderna suggests that the proposed amicus brief is improper because

it does not comply with the formatting and timing guidelines in the Federal Rules of Appellate Procedure. Opp. 5. But those rules do not govern here, where the page limits and briefing schedule are different, as Moderna appears to tacitly acknowledge by using a “Cf” citation. And the fact that the brief uses 12-point font rather than 14-point because it was initially filed before a court with different standing rules is not a reason to deny the motion. If the Court prefers, Arbutus and Genevant will refile the brief in 14-point font.

Fourth, there is no reason for the Court to credit Moderna’s hyperbolic claim that accepting the proposed amicus brief would “set a precedent for regular cross-filing of briefs, potentially doubling the papers for the life of this litigation and creating undue risk of collateral conflict with Judge Goldberg.” Opp. 2. The fact that the parties submit a single additional brief on an important legal issue does not suggest that there is any broader overlap on any other issues in the case. Moderna’s brief identifies no reason to believe there is. And far from ***creating*** a risk of collateral conflict, the proposed brief actually would help ***avoid*** such conflict by better elucidating this parallel issue, currently under consideration by another court in this District, before this Court renders its decision.

Finally, the fact that Arbutus and Genevant are aligned with one of the parties to this litigation on a legal issue before the Court does not mean that an amicus brief is improper. Indeed, anytime a party seeks to submit an amicus brief to the Court

on a legal issue, it is because that party has some interest in the outcome of the court's ruling on that issue. *See, e.g., Neonatology Assocs.*, 293 F.3d at 131, 132 (rejecting "appellants' argument that an amicus must be an impartial person not motivated by pecuniary concerns" and noting "it is not easy to envisage an amicus who is [financially] 'disinterested' but still has an 'interest' in the case" as required by Fed. R. App. P. 29). The cases Moderna cites are not to the contrary. For example, *Leigh v. Engle*, 535 F. Supp. 418 (N.D. Ill. 1982), dealt with the unique circumstance of the Secretary of Labor seeking to intervene in a private litigation. As the Court noted, "[t]he defendants in this case are entitled to have their contentions and arguments on the summary judgment motions considered without having the weight of the United States, speaking through the Secretary of Labor, joining plaintiffs." *Id.* at 422. There is no such concern here. And although Moderna argues that the Court should deny leave because the proposed *amici* raise no interest that is not already represented by plaintiff (Opp. 7), the Third Circuit has held that "[e]ven when a party is very well represented, an amicus may provide important assistance to the court." *Neonatology Assocs.*, 293 F.3d at 132.

At bottom, as the Third Circuit has emphasized, "it is preferable to err on the side of granting leave" because if the amicus brief turns out to be unhelpful, this Court can "simply disregard" it; but "if a good brief is rejected, the [Court] will be deprived of a resource that might have been of assistance." *Id.* at 133.

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CERTIFICATE OF COMPLIANCE

I hereby confirm that this brief complies with the type and number limitations set forth in the Standing Order. I certify that this document contains 1,301 words, which were counted using the word count feature in Microsoft Word, in 14-point Times New Roman font. The word count does not include the cover page, tables, or the counsel blocks.

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